Discursive Typologies and Moral Values in Stem Cell Politics, Regulation and Commercialisation

Bruce, A. & Harmon, S. H. E. Jul-2009 In : Journal of International Biotechnology Law. 6, 2, p. 61-66
Doi: 10.1515/JIBL.2009.10. The final publication is available at www.degruyter.com.

DISCURSIVE TYPOLOGIES AND MORAL VALUES IN STEM CELL POLITICS, REGULATION AND COMMERCIALISATION: SOME PRELIMINARY OBSERVATIONS

Ann Bruce[♥] & Shawn H.E. Harmon[♠]

Abstract: Great importance is attached to, and great controversy surrounds, biotechnology generally and stem cell research more specifically, particularly human embryonic stem cell research. Given its position at the vanguard of innovations in theoretical and applied human healthcare science, and as a source of political conflict and achievement, it is useful to examine attitudes toward, and actions around, embryonic stem cell research. This article conceives of three discursive typologies and explores their deployment in three different settings or sites in the life or progress of embryonic stem cell research, namely, the political (determining legal boundaries), the hybrid (identifying and enforcing boundaries for laboratory research), and the administrative (enforcing boundaries in the commercial context), the intention being to determine whether these typologies are consistent and what moral values their use supports. This article concludes that the typologies are deployed to varying degrees in the different sites, and with varying degrees of success. Although this might be expected, and not altogether unwarranted, given the different roles and objectives of the primary institutions at each site, the current prevalence of the typologies suggests that these institutions might not be operating optimally from the democracy enhancement and transparency points of view.

INTRODUCTION

It is perhaps now trite to say that great importance is attached to, and great controversy surrounds, biotechnology generally and stem cell research (SCR) more specifically, particularly human embryonic stem cell research (ESC). There are a variety of ESC-based applications under development, the lead one being treatment for spinal cord injury developed by Geron Corporation and awaiting US Food and Drug Administration approval for clinical trials.[1] Similarly, there is a plethora of ethical issues that must be navigated by those in the field, including appropriate and sensitive sourcing of embryos (and donor consent), respectful treatment of the embryo during research, avoidance of prohibited activities in relation to embryos (reproductive cloning, chimeric production, etc.), appropriate commercialisation of

♥ Senior Research Fellow, INNOGEN, ESRC Centre for Social and Economic Research on Innovation in Genomics, PhD Candidate in Social Science, the Open University. BSc 2.1, University of London (1981); MSc, University of Edinburgh (1983).

♠ Research Fellow, INNOGEN, ESRC Centre for Social and Economic Research on Innovation in Genomics, PhD Candidate in Law, University of Edinburgh, and Member of the Nova Scotia Bar. BA, Saint Mary's University (1993); LLB, University of New Brunswick (1996); LLM, University of Edinburgh (2004).

[1] See http://www.geron.com/, and http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-0471t1-01.htm.

ESC-derived products, and more.[2] Much has happened in the relatively short lifespan of ESC research, and in many ways, it has become the hot health science of the new millennium. Given its position at the vanguard of innovations in theoretical and applied human healthcare science,[3] and at the pinnacle of political conflict,[4] and legal achievement,[5] there is significant utility in examining attitudes toward, and actions around, ESCR.

This article undertakes one element of that examination. It conceives of three discursive "typologies"[6] and explores their deployment over time and in different settings:

(1) a sampling of the debates which lead to the adoption of the *Human Fertilisation and Embryology (Research Purposes) Regulations 2001* (2001 Regulations)[7] in the UK;[8]

(2) an application to vary a license permitting derivation of ESC lines using nuclear transfer and parthenogenetically activated oocytes, and the consequent decision by the Human Fertilisation and Embryology Authority (HFEA) [9] and

---

[2] For more on these, see The UK Stem Cell Initiative, *Report and Recommendations of The UK Stem Cell Initiative* (2005), at http://www.advisorybodies.doh.gov.uk/uksci/uksci-reportnov05.pdf, EMB, *Stem Cell Research: Status, Prospects, Prerequisites* (2006), at http://www.embo.org/scisoc/stem_celli.pdf, F. Fukuyama & F. Furger, *Beyond Bioethics: A Proposal for Modernizing the Regulation of Human Biotechnologies* (2006), at http://www.isscr.org/about/index.htm, and many more.

[3] Although it is conceded that there is perhaps inadequate support for basic science, ground-breaking projects are underway which will have implications (in the not too distant future) for pharmaceutical toxicity testing, genetic diagnostics and stem cell therapies: DLA Piper & Scottish Stem Cell Network, "Commercialisation Strategies in Regenerative Medicine" Workshop, 17 July 2008, Edinburgh.

[4] With respect to conflict, we note the heated Parliamentary debates that preceded the adoption of both the *Human Fertilisation and Embryology Act 1990* and the *Human Fertilisation and Embryology (Research Purposes) Regulations 2001*, as well as that surrounding the recently back-burnered *Human Fertilisation and Embryology Bill 2007*, which amends the regime created by the former instruments: see M. Mulkay, "Rhetorics of Hope and Fear in the Great Embryo Debate" (1993) 23 Social Studies of Science 721-742, S. Parry, "The Politics of Cloning: Mapping the Rhetorical Convergence of Embryos and Stem Cells in Parliamentary Debates" (2003) 22 New Genomics & Society 177-198, and the ongoing coverage of recent activities in Bionews (http://www.bionews.org.uk/).

[5] With respect to achievement, we note the widely held view that the UK's reproductive medicine regime is a pragmatic but principled and durable system that has appropriately been emulated, at least in part, in jurisdictions around the world: see Department of Health, (2005), *Review of the Human Fertilisation and Embryology Act: A Public Consultation*, at http://www.dh.gov.uk/en/Consultations/Closedconsultations/DH_4123863, and House of Commons Joint Committee on the Human Tissue and Embryos (Draft) Bill (2006), *First Report of the House of Commons Joint Committee on the Human Tissue and Embryos (Draft) Bill*, available at http://www.publications.parliament.uk/pa/jt200607/jtselect/jtembryos/169/16901.htm.

[6] The "typologies" explored represent different ways of expressing views rather than the actual views expressed; they are the main types of arguments being made by stakeholders.

[7] SI 2001/188, available at http://www.opsi.gov.uk/SI/si2001/20010188.htm.

[8] Specifically, the Hansard for the House of Commons debates on 17 November 2000 and 19 December 2000, and in the House of Lords on 22 January 2001, both available at http://www.publications/parliament.uk/pa/.

[9] Specifically, the Minutes of the HFEA's Research Licence Committee meetings held on 17 May 2006, 11 July 2006, and 14 September 2006, all available at

(3) an example of a challenge to the patenting of an ESC-based invention, and the consequent decision of the European Patent Office (EPO).[10]

These three nodes represent three distinct sites in the life of ESC research, from the purely political (determining legality), to the mixed political and administrative or hybrid (determining and enforcing technical boundaries), to the more traditionally administrative (permitting/enforcing monopoly rights over ESC-derived inventions).

At the outset, we acknowledge our indebtedness to the discursive analyses that have preceded (and informed) this article. For example, after extensive interviews and studies, Tait offered an approach to understanding the basis of arguments surrounding regulation of genetically modified crops in the EU, identifying two main types of arguments: (1) interest-based characterised by a willingness to change with evidence, is restricted to specific applications, and is typified in the negative by the statement "not-in-my-backyard"; and (2) value-based, characterised by a commitment to a specific value-basis, is not open to change with evidence, and is typified in the negative by the statement "not-in-anybody's backyard".[11] She concluded that the risk regulatory approach originally applied to the release of GM crops was historically developed to negotiate interest-based arguments, but that there was no mechanism for expressing value-based (or alternative-futures based) concerns except as and through risk-based procedures, thereby exposing a mismatch between regulatory instruments and individual concerns. Later, and on a different path, Evans examined interest and value-based arguments in the US human genetics research setting, concluding that the American policy debates tended to narrow so that only interest-based views (which are easier for regulators to deal with) were considered.[12]

The above suggests that the arenas of discursive analysis and regulatory interaction with interests and values are both fruitful and important areas of research which can contribute to our understanding of both policy-making processes and outcomes, and of the motivations underlying the choice of particular policy paths over others. The present article is a case study based on a sampling of data to develop a preliminary analysis on (1) whether different typologies are represented to different degrees in different sites, and, if so, whether this is appropriate and what this says about the institutions at these sites, and (2) what moral values are engaged or advanced by the deployment of these typologies.

I. THE TYPOLOGIES EXPLORED: WAYS TO DEFEND/ATTACK STEM CELL RESEARCH

Three general types of arguments (or typologies) are considered,: (1) the Core Values (or Red / Green Button Issues) typology; (2) the Evidence-to-Consequence (or Crystal Ball) typology; and (3) the Competing Interests (or See-Saw) typology, citing

---

http://www.hfea.gov.uk/docs/Variation_of_licence_to_include_additional_sources_of_eggs_for_research.pdf.

[10] Specifically, the Minutes of the EPO's Opposition Division proceedings on 22 July 2002, and the Opposition Division's Written Decision dated 21 July 2003, both available at http://www.epoline.org/portal/.

[11] J. Tait, "More Faust than Frankenstein: the European Debate about the Precautionary Principle and Risk Regulation for Genetically Modified Crops" (2001) 4 Journal of Risk Research 175-189, at 179.

[12] J. Evans, *Playing God? Human Genetic Engineering and the Rationalization of Public Bioethical Debate* (London: University of Chicago Press, 2002).

examples of their use by interviewees during recent empirical research.[13]

(1) The "Core Values" or "Red / Green Button Issues" Typology

Arguments under this banner are grounded on and seek to advance fundamental values (ie: values that the advocate esteems and feels should be respected). Such arguments are closely associated with deontological ideas insofar as they are concerned with morality and duties, and they may well be influenced by entrenched (or hard-to-change) cultural ideas about good and bad. Ultimately, this typology questions whether there are barriers that we should not be breaking, or, alternatively, absolute goods that we must be seeking.[14] From a structural point of view, they often begin with a description of "how things are", and then shift into a consideration of what elements of this reality must be maintained or changed to advance the values deemed most worthy. Thus, from a basic starting opinion of how things are (which is not necessarily evidence-based), a position is taken and a number of conclusions are believed to flow from this.

As suggested above, the epistemology of value positions varies from person to person, with sources ranging from sacred texts, to scientific texts, to values transmitted from person to person over time (ie: cultural presuppositions or culture-based ideals). Where fundamental values are derived from sources that are not shared by advocates, there are reduced possibilities for meetings of the mind. For example, values based on sacred texts may be viewed as "irrational" to those not sharing them, but viewed as completely consistent and rational within the context of the advocate's value system.[15] Alternatively, scientific arguments may be viewed as excessively reductionist and limited to too narrow a range of issues by those whose positions include consideration of wider aspects (eg: the appropriate relationship of humans to each other).

In the ESC research context, fundamental values are most commonly deployed (either consciously or otherwise) in assessments of what it is to be human, and, what, if any, limits should be erected in relation to scientific research. For example, values emergent from the advocate's opinion of what it means to be human are brought to bear on the embryo, and they determine whether an embryo is considered to have full moral status, on the one hand, or no moral status, on the other, or something in-between. The following are examples of arguments made during the empirical research that fall within this typology:[16]

---

[13] A. Bruce, "Interests and Values in Risk-Related Stakeholder Interactions Project" (see http://www.genomicsnetwork.ac.uk/innogen/research/governanceregulationandpublicinterest/projecttitle,2509,en.html). Bruce conducted one-hour interviews with specialist stakeholders in the SCR community between October 2004 and December 2005. Interviewees were targeted to cover as wide a range of views as possible, and included research scientists and technicians, people in the industrial and policy-making sectors, consultant physicians, and members of pro and anti-ESCR advocacy groups. Interviews were recorded and transcribed and subsequently analysed.

[14] As suggested by the above, although value-based arguments are often depicted in the negative (ie: the absolute moral status of the embryo serves as a restriction on research), the opposite pole (ie: all research on embryos should be allowed) must also be based on fundamental values since there is no *a priori* reason for taking one stance rather than the other. In short, there are a lot more value-based arguments being made than typically get accepted in popular (and academic) media.

[15] This phenomenon has been referred to as "value rationality" as opposed to "instrumental rationality": see M. Weber, *Economy and Society: An Outline of Interpretive Sociology*, vol. 1 (NY: Bedminster Press, 1968).

[16] It should be noted that neither these examples, nor the ones identified below, represent an exhaustive list of the use of these typologies during the empirical research.

- The moral status of the embryo is that of a fully-grown adult human. We would not carry out research like this on other humans, so we shouldn't conduct such (destructive) research on embryos either.

- An embryo has no moral status; it is just a ball of cells obtained through biopsy. Thus, there are no problems with using them in socially beneficial research.

- Humans are valuable and should never be instrumentalised. Creating embryos for research transforms humans into, and treats them as, a resource, which is disrespectful and wrong.

- Helping others is an absolute good. Science and researchers have responsibilities to provide cures and therapies to people in need.

Of course, as demonstrated above, because the opinion of "how things are" is informed by fundamental values – which are often deep-lying and ingrained – opinions can be taken for granted (held with very little critical assessment), assumed to be shared (considered self-evidently good and universal), and static (unlikely to be significantly altered by evidence or arguments from different value perspectives).[17] Moreover, as suggested above, arguments of this type are triggered by emotive or "red button / green button" issues.

(2) The "Evidence-to-Consequence" or "Crystal Ball" Typology

Arguments of this type, though often value-laden, are future(s) oriented and tend to rely on some evidence base. Indeed, their utilisation of evidence makes them seem much more objective than the previous typology insofar as they seem more provable. However, poorly understood natural phenomena, scientific uncertainties, the very nature of horizon-gazing, and the influence of culture (again) all introduce variables over which there is much to debate (from an evidentiary point of view). For example, while most would agree that there is some value in SC research, advocates of the different types of SC research often disagree over the prospects for each type of research, each drawing on current scientific evidence. Disagreements over their future potential may stem from:

- diverging opinions as to the rigour and meaning of previously reported research; or

- conflicting judgements on potentiality based on past experiences (eg: one's experience with the difficulties of tissue engineering may make one more sceptical of the promises of ESC research).

Whatever their basis, it is clear that there is no absolutely neutral or purely objective scientific evidence (or interpretation of the evidence). As such, while an evidence-based approach may appeal to technocratic systems of decision-making, and while it

[17] I It is worth mentioning that it is quite rare for fundamental values to be held absolutely (or absolutely consistently).

is certainly an important component of any decision-making process, it is unlikely to be capable of dealing satisfactorily with the complexities inherent in contentious areas of science such as SC research. In short, a purely evidence-based approach will frequently fail to finally (or persuasively) adjudicate between options, particularly where options have a value-informed component,[18] but that does not diminish their power when deployed expertly (as is often the case in ideological or contested political settings).

As suggested above, this typology uses concepts of the future, or what constitutes a desirable future, and whether particular developments are moving society toward or away from that future, and it marshals (often contested) evidence in support of the position taken. The empirical data obtained disclosed the following arguments which exemplify this typology:

- The knowledge gleaned from ESC research will encourage reproductive cloning and/or genetic modification of humans, which turns humans into manufactured entities and is therefore undesirable.

- Commercial interests are driving ESC research with the result that outcomes are not targeted at the greatest human needs, but rather at the greatest short-term profit (evidence offered), with the result that research will benefit primarily (or only) the rich or may be undertaken for unworthy endeavours such as cosmetic benefits.

- The potential from adult SC research is currently underestimated, and will ultimately produce more benefit than ESCR.

- The use of human embryos in research is ethically questionable (evidence offered), and we should be wary of creating a world where human embryos are routinely used.

- There exists a huge need for medical innovation (evidence offered), and the consequences of not pursuing ESCR will be more negative than the consequences of doing it.

These arguments make clear the deployment of evidence, the identification of trends, and the consequentialist bent of this typology; common starting positions were evidence-based claims followed by inquiries about the consequences of doing (or not doing) something, and whether those consequences were good or bad. They demonstrate the difficulties (and shortcomings) of trying to "crystal ball" in the innovation environment, but also the inevitability of doing so given the requirement for research to be regulated in advance of knowledge of its outcomes.

(3) The "Competing Interests" or "See-Saw" Typology

This category of argument is implicitly founded on an identification with interests and

---

[18] Examples of this shortcoming in evidence-based approaches are available from other areas of technology. For example, the difficulties encountered in risk assessments in the environmental setting suggest that making decisions purely on the basis of what looks like impartial evidence is unlikely to provide solutions that are acceptable to everyone.

pragmatic considerations of who wins and who loses. Interest-based arguments are often caricatured as being based on self-interest, but one can (and interviewees often did) advance interest-based arguments that served the interests of groups to which the advocate does not belong (eg: marginalised or vulnerable groups). However, it is also not always inappropriate to focus on the interests of the self, particularly where individuals have valuable insights that others cannot imagine or predict. For example, an individual may be so situated that only s/he can describe what it is like to be in particular circumstances (eg: people with a diagnosed illness are best positioned to explain the difficulties engendered by, and the unfolding consequences of, that illness).

The following are examples of arguments made during the interviews that are categorised as interest-based in nature:

- We (society) need to balance the unmet needs of the sick with a sensitivity towards the embryo.

- If we are to proceed with ESC research, then we must employ appropriate consent procedures with respect to embryo donors to ensure their interests are protected.

- Throwing spare embryos away is much worse than using them for SC derivation.

- The elderly are too often marginalised in our society, and SC-based therapies are potentially more likely to be of benefit for them.

One can see from the above that arguments of this typology are often directed at trying balance out interests (so winning and losing isn't such a stark, zero-sum game). Although advocates deploying these arguments might (seem to) vacillate or "see-saw" back and forth on a given point, interest-based arguments can be valuable for exposing a wider range of relevant considerations, and should not be dismissed as being less worthy than other types of argumentation.

(4) Summation: A Variety of Tools for a Controversial Subject in a Plural Society

The above does not (nor could it ever) capture the full richness and nuance of the interviewees' views. However, it offers a suitable basis by which one can reasonably articulate and differentiate the typologies, accepting, of course, that they overlap and interact intimately; a single typology can be used to encourage ESC research or, in the mouth of another, to constrain it, and one's position on ESCR can be advanced under any or all of the typologies discovered. For example, one might advance a position antagonistic to ESC research as follows:

- Core Values Argument: The embryo is akin to a fully formed human and must be respected and treated as such, and to use it in research is ethically questionable.

- Evidence-to-Consequences Argument: The consequences of pursuing ESCR, being the advancement of cloning knowledge and increasing likelihood of

human modification, may well be more negative than seeking (potentially less effective) therapies through other means.

- Competing Interests Argument: The unmet needs of the sick must be balanced against the very real needs of the embryo and a sensitivity towards the position of the infertile women (embryo donors), who constitute a vulnerable group.

In short, moving between typologies in advancing a position, whether deliberately or accidentally, is neither uncommon nor difficult, with the result that value-based arguments often get tangled up with, or transformed into, interest-based arguments (ie: an argument may change over the course of its advancement). This entanglement does not diminish the value of the typologies for assisting us in making sense (through categorisation) of what is occurring in the maelstrom that is ESCR politics and regulation, but it means caution and attention to what people are saying (and whether they are saying it consistently) is important..

II. THE SITES EXAMINED: THE TREATMENT OF STEM CELL RESEARCH "IN THE WORLD"

Having identified the typologies (and indeed some of the substantive arguments), it is appropriate to consider their deployment "on the ground in the real world", and more particularly variations in dependence on the different typologies in different fora. We now examine the appearance of these typologies in three different settings within the ESC research arena, each one illustrating a different site of science governance, namely the political (determining legal boundaries), the hybrid policy-administrative (identifying and enforcing boundaries for laboratory research), and the administrative (enforcing boundaries in the commercial context). The intention is to examine the types of arguments made, not to conduct any ethical analysis of them; the emphasis here is on process rather than substance, and the exercise is interpretive rather than evaluative.

(1) Stem Cell Politics: Determining the Legal Scope of SCR

The UK's legislative position on ESCR – the 2001 Regulations – is both dependent on, and a predictable extension of, the debates which preceded it and lead to the original HFEA 1990 (eg: the work of the Committee of Inquiry into Human Fertilisation and Embryology, chaired by then Dame Mary Warnock).[19] Very generally, it was opined by the majority of the Warnock Committee,[20] and accepted for purposes of the subsequent legislation, that embryos, though not having the same moral status as adults and other animals, have a special moral status which demands that any research undertaken on them complies with certain criteria and limitations. As such, not only the permissibility of embryo research, but its association with special protection, was established prior to the discovery of ESCs.

---

[19] See S. Parry, *supra*, note 4, D. Morgan, "Ethics, Economics and the Exotic: The Early Career of the HFEA" (2004) 12 Health Care Analysis 7-26, and S. Harmon, "Control of Reproductive Treatment and Research: From the Moral to the Political to the Legal – and Back Again? or 'There and Back Again, A Regulator's (Hobbit's) Odyssey (Holiday)'" in C. Lyall *et al.* (eds.), *The Limits to Governance* (Aldershot: Ashgate, 2008) (forthcoming).

[20] Department of Health, (1984), *Report of the Committee of Inquiry into Human Fertilisation and Embryology*, 1984, Cmnd 9314.

According to some, the Parliamentary debates on the 2001 Regulations demonstrated a distinct lack of will (on the part of the government) to accept any new ethical issues for discussion, or to re-open debates about the status of the embryo.[21] Hauskeller argues that the UK's rather liberal ESCR regulations (within Europe and particularly compared to Germany) can be understood as an outcome of the tendency to prefer utilitarian, case-by-case ethical reasoning over broader deontological considerations. When SC research became a reality in late 1998, she argues, embryo research had already become "a regulated but normal practice in Britain".[22] Similarly, Banchoff explains that the different regulatory approach adopted by the UK (again as compared to Germany) can be explained, at least in part, by history. The political institutions empowered a powerful pro-research coalition and the Prime Minister, who advocated a liberal stance on SC research, was able to push an agenda characterised by solidarity with the sick over that of embryonic life.[23]

This, then, is the environment to which we now briefly turn, considering in particular the relevant political debates undertaken in the House of Commons on 17 November 2000 and 19 December 2000, and in the House of Lords on 22 January 2001. We examine the types of arguments made as informed by our proposed typologies, not the rhetorical devices that were used, nor the appeals to the character of the pre-existing institutions that were made.[24] So situated, let us turn to the political debates and seek to identify the typologies. Quotes have been selected to be illustrative of the types of argument being made.

It should perhaps come as little surprise that the Core Values (or Red / Green Button Issues) typology is used frequently, most often in relation to the status of the embryo. It should also come as little surprise that such arguments have been deployed in support of positions on both sides of the issue, namely in support of the previous finding that embryo research is permissible within constraints, and in support of the claim that embryo research (and ESC research) is abhorrent. For example, the following two excerpts constitute claims to values that should be upheld:

> The 1990 Act endorses the principle in the Warnock Report that a measure of respect should be accorded to embryos, and that research involving embryos should be subject to moral constraints and regulation. That is absolutely right.[25]

> As a mother and a grandmother … the fact that we have scientists who think of these [embryos], who are definitely human, simply as a source to be exploited in obtaining cells and tissue, I find frightening.[26]

Another Parliamentarian, in an argument that also discloses shades of the Competing

---

21 See S. Parry, *supra*, note 4, C. Hauskeller, "How Traditions of Ethical Reasoning and Institutional Processes Shape Stem Cell Research in Britain" (2004) 29 J Medicine and Philosophy 509-532, T. Banchoff, "Path Dependence and Value-Driven Issues: The Comparative Politics of Stem Cell Research" (2005) 57 World Politics 200-230, and others. See also the opening statements of Yvette Cooper, Under-Secretary of State for Health, House of Commons Hansard, 17 November 2000, col. 1175, which defer to the debates preceding the adoption of the HFEA 1990 and express a desire not to repeat them.

22 C. Hauskeller, *ibid*, at 515.

23 T. Banchoff, *supra*, note 21.

24 Which analyses have been undertaken elsewhere: see S. Parry, *supra*, note 4, and others.

25 House of Commons Hansard, 17 November 2000, col. 1180.

26 House of Commons Hansard, 17 Nov 2000, col. 1204.

Interests typology, argued that there exists a moral imperative to allow research into life-saving therapies:

> I am driven to my view on the issue not by science, although that is an important factor, but by the ethical duty I believe we as representatives have to do what is right. After careful examination, I have judged that, although it will entail the curtailment of the rights of some early embryos, allowing research into life-saving therapies is the right thing to do.[27]

Contrary to this, questions were raised over the value properly attributed to science and scientists and the (fundamental?) right to pursue science (the BSE crisis and other events having shaken belief that scientific activity is benign or neutral), and value-based arguments were made against the apparent free-reign given to researchers. For example, it was suggested that, "the age of deference to scientists is over. It will seem to many people that science has failed us in many spheres, and the fact that there is a lack of proper control over scientists is – with, as always, the great benefit of hindsight – obvious."[28]

The Evidence-to-Consequence (or Crystal Ball) typology was also used. Although some stressed the huge potential of ESC research to produce future cures for degenerative diseases, while others recognised the uncertainty around future developments, many still considered research to be inherently worthwhile. For example:

- "[Embryonic stem cells] … have huge potential because, if scientists can understand how they work, it may be possible to re-programme adult cells providing the potential to develop treatments and cures for all sorts of degenerative diseases"[29]

- "The view of the Chief Medical Officer's expert group was that the long-term promise of stem cells from adult tissue could equal or surpass that of embryonic stem cells. However … many scientists believe that research into embryonic stem cells is vital." [30]

- "None of us knows exactly what discoveries stem cell research could lead us to … but potentially revolutionary treatments lie within our grasp." [31]

- "As a non-scientists, I cannot know whether even that analysis is right. I do not know whether stem cell research – adult and embryonic – will ever deliver a solution to Parkinson's. However, we should allow those who have identified potential in that route the chance to realise the ambition of a solution to the disease." [32]

The future was also presented in negative terms, either as a dangerous journey with an

---

27 House of Commons Hansard, 17 Nov 2000, col. 1217.
28 House of Commons Hansard, 17 Nov 2000, col. 1284.
29 House of Commons Hansard, 17 Nov 2000, col. 1178.
30 House of Commons Hansard, 17 Nov 2000, col. 1178.
31 House of Commons Hansard, 17 Nov 2000, col. 1182.
32 House of Commons Hansard, 17 Nov 2000, col. 1200.

unknown destination, or a journey leading inevitably to disaster (ie: to human reproductive cloning):

- "[People] may also be alarmed at the danger of embarking on a journey the destination of which is unclear to many of us at this point."[33]

- "Moreover, although the Government assert that they are completely opposed to reproductive cloning – I imagine that everyone in the House must take that view – Lord Winston, among other fertility experts, has affirmed that therapeutic cloning will lead to reproductive cloning within twenty years."[34]

- "It is true that if the [2001 Regulations] are not introduced, the research is likely to continue in other countries where there may be no regulatory framework to govern either the way in which … research takes place, or the purposes of the research."[35]

The latter representation in particular is an excellent example of an MP crystal-balling a (near) future in which the research is not permitted, the claimed consequence being that research will proceed in other jurisdictions with no or less palatable regulation, and, additionally, domestic entities (pharmaceutical and biotech companies) will therefore lose out (and be injured) for no good reason.

The Competing Interests (or See-Saw) typology is reflected in comments that imply a search to find a balance in the weight given to specific groups. For example:

- "How many of the letters that his constituents have sent him arose from a genuine individual interest in the matter, and how many may have been prompted by interests groups or even – who knows – by faith groups?"[36]

- "I know that it is right that in all we do in our personal lives we should be guided by our beliefs, but I have some difficulty when those beliefs are imposed on others."[37]

It is also implicated in concerns over the weight that should be given to scientific arguments and to supporting the UK pharmaceutical and research base:

- "It is clear that the scientific arguments are all on one side, which is to extend the Human Fertilisation and Embryology Act 1990."[38]

- "… [B]ut does he accept that the key issue at stake in the Government's introduction of these regulations is the defence of the United Kingdom's pharmaceutical and biotechnological research base?"[39]

There is also evidence that consideration was given to the balance that must be

---

33 House of Commons Hansard, 17 Nov 2000, col. 1183.
34 House of Commons Hansard, 17 Nov 2000, col. 1206.
35 House of Commons Hansard, 17 Nov 2000, col. 1230.
36 House of Commons Hansard, 17 Nov 2000, col. 1184.
37 House of Commons Hansard, 17 Nov 2000, col. 1195.
38 House of Commons Hansard, 17 Nov 2000, col. 1194.
39 House of Commons Hansard, 17 Nov 2000, col. 1194.

achieved between our duties to the sick and our duties to the embryo. For example, Dr. Evan Harris MP stated that, "What I will argue more cautiously is that our duties towards the sick and vulnerable (which I take to be at the heart of Jewish and Christian ethics) should finally be given priority over our duties to those embryos that should never be implanted."[40] Additionally, there were questions posed about what weight should be given to the fact that embryos are destroyed in ESCR when, as "spare" embryos in IVF treatment, they would be destroyed anyway. For example, Dr. Michael Clark MP queried, "what is the logic of continuing with IVF treatment, producing 237,000 embryos more than we need, and destroying them rather than allowing them to be used for research that could benefit others?"[41]

On the whole, then, the Parliamentary debates can be characterised as "rich" insofar as they disclose the deployment of all three typologies in support of (and against) a range of possibilities. From this, we can conclude that, from a purely discursive point of view, the full range of our argument types were made and considered in the establishment of a regulatory framework for ESC research. Although, we draw no conclusions in this assessment as to the efficacy of each type of argument from the point of view of changing opinions or marshalling support, we would suggest that reliance on all of these discursive tools is encouraging from a democracy-in-motion point of view. They suggest a full airing of opinions and, more importantly, a range of means of presenting evidence and/or making a point. This, of course, is to be encouraged.

The pressures on Parliamentary time, however, are such that these debates take place relatively infrequently. One might note the massive scientific changes that had taken place between the adoption of the HFEA 1990 and the time the 2001 Regulations were being considered. During that scientifically dynamic time, the implementation of the HFEA 1990 had been the responsibility of the HFEA, and it is to that institution that we turn next.

(2) Stem Cell Policy and Administration: Identifying and Enforcing Boundaries for Scientific Activity

Having considered the political arena (ie: the gestation of the law), we now turn to a more complex site in which the law is interpreted, shaped, and applied in a dynamic setting; a site which is dominated by the HFEA, an independent statutory body established in 1991 and charged with both advising government and overseeing the use of gametes and embryos in fertility treatment and related research.[42] We examined the Minutes of the HFEA's Research Licence Committee (RLC) for meetings held on 17 May 2006, 11 July 2006, and 14 September 2006, in relation to the Newcastle Fertility Clinic's application to vary the licence for Research Project R0152 (a project to derive ESC lines using nuclear transfer and parthenogenetically activated oocytes).[43] Again, the intention is not to evaluate the effectiveness of the

---

40 House of Commons Hansard, 17 Nov 2000, col. 1218.

41 House of Commons Hansard, 19 Dec 2000, col. 250.

42 See s. 8, HFEA 1990. For more on the HFEA, see http://www.hfea.gov.uk/. This dual function has given rise to some tension and much criticism: see D. Morgan, "Ethics, Economics and the Exotic: The Early Career of the HFEA" (2004) 12 Health Care Analysis 7-26, and House of Commons Select Committee on Science and Technology, *Human Reproductive Technologies and the Law: Fifth Report of Session 2004-05* (2005), available at http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/702.htm.

43 This application was chosen because it represents an attempt to amend an existing licensed project by expanding the scope of embryo sourcing via processes that are quite controversial. Of equal

HFEA, but to analyse the typology of arguments that are utilised in the few publicly available records generated by the application.

As a statutory body, the RLC must comply with its empowering provisions, in this case s. 3 of Schedule 2 of the HFEA 1990 (as amended by the 2001 Regulations). In conformity with that provision, the RLC adopted a very structured (almost ritualised) approach to evaluating research proposals, generally employing a three-step process:

- Step 1: The research activity is identified and the RLC ascertains that it is not prohibited under the HFEA 1990 and 2001 Regulations.

- Step 2: The RLC determines whether the research activity is necessary or desirable for the purposes of (a) increasing knowledge about the development of embryos, (b) increasing knowledge about serious disease, or (c) enabling any such knowledge to be applied in developing treatments for serious disease.

- Step 3: The RLC addresses the question of whether an increase in the number of fresh eggs is needed.

In the subject application, Newcastle sought permission to source human eggs in two new ways: (1) through altruistic donation for the express purpose of research;[44] and (2) through egg sharing arrangements.[45] Having already issued a licence, the RLC accepted without comment that the research was not prohibited. It accepted the clinic's report that it was obtaining some 66 fresh eggs annually by donation of surplus from fertility patients, and it was prepared to accept that, "a lack of fresh eggs was delaying progress with the project [and] this new source of fresh eggs would be desirable for the project because it would increase the number of fresh eggs available to the researchers."[46] However, it questioned whether fresh eggs were really "necessary" for the research, and it was on this issue that the application turned.

With respect to altruistic donation, the RLC initially held that the discomfort and clinical risk faced by the woman undergoing an egg retrieval procedure (for purely altruistic purposes) outweighed the applicant's need to supply fresh eggs for its research, noting parenthetically some of the ethical issues around egg donation implicated by the conduct of Dr. Hwang, the discredited South Korean scientist.[47] In response to this, the applicant argued that (1) the evidence in favour of fresh eggs was much stronger than stated by the RLC, (2) the risks associated with their collection were manageable within their clinic, and (3) there was precedent for altruistic egg donation for fertility treatment and for research which does not require a licence from the HFEA.[48] In light of these representations, and with the imposition of additional

---

importance, however, was the fact that it represents one of the few applications supported by publicly available written documents, as opposed to merely a summary on the HFEA website.

44 The term "altruistic donation" describes a process whereby a person who is not undergoing fertility treatment is nonetheless willing to undergo hormone stimulation and egg retrieval purely for the purposes of donating the resulting eggs to the research project.

45 The term "egg sharing" describes a process whereby patients undergoing fertility treatment are prepared to donate a share of their eggs to the research project in return for receiving reduced costs for the fertility treatment.

46 RCL Minutes, 17 May 2006, at para. 7.

47 RCL Minutes, 17 May 2006, paras. 8 and 9.

48 RCL Minutes, 14 September 2006, paras. 3, 4 and 5.

precautions so as to reduce the potential for coercion,[49] the RLC overturned its initial decision and permitted the sourcing of eggs through altruistic research-specific donation.

With respect to egg sharing, the RLC appeared to be influenced by the realisation that women participating in egg sharing would still have to pay part of the costs of their fertility treatment, and this payment would be more than when egg sharing with other patients purely for fertility treatment purposes. In short, additional financial incentives would not strongly influence (or coerce) women in their decision to donate eggs for research. Moreover, the woman would not be exposed to any additional risk or pain because she would be undergoing the egg retrieval anyway. Finally, the egg sharing consent form would be completed by the woman when accompanied by a member of the clinical team not involved in the research. Given all of the above, the RLC was satisfied that egg sharing was acceptable.[50]

As is obvious from the above, both of the proposed new sourcing procedures were considered primarily within the rubric of a competing interests approach. Although one could argue that an Evidence-to-Consequence approach was also taken insofar as the RLC considered, at least in passing, the practical outcome of a coercive environment obtaining, and the evidence suggests that Newcastle advanced and supported its position by arguments from the Competing Interests (or See-Saw) typology. Ultimately, the RLC took care to balance risks and benefits, failing completely to engage with the core values arena. From a discursive perspective, then, it deployed only one (debatably two) of the typologies.

This should not necessarily be taken as a defect in the way in which the HFEA handled the application or performed its function. As a law-administering body with a specified remit, it is appropriate for the HFEA to rely on transparent and reproducible procedures that comply with provided policy criteria which are to be implemented again and again over time. It is perhaps appropriate that the range of typologies which arise in this setting should contract from that evident in the political setting, and that the objectives for which they are deployed should narrow. However, we must recall two unique facets of the HFEA which separate it from the usual administrative, policy-implementation body.

First, the HFEA is applying the law in a realm of rapid change (ie: technologies evolve, societal perceptions change, the nature of requests/applications transforms). In such a setting, accretion occurs whereby the law is required to address, and the HFEA is required to respond to, unanticipated scenarios. Administrative agencies often refrain from foraying into such new areas, citing the need for Parliament to amend/expand its statutory authority before it could act, but the HFEA has taken a more robust view of the scope of its authority, perhaps mindful of the nature of science and the general desire for the UK to remain competitive.[51] The result is that the HFEA can potentially become disengaged from its original remit; as decisions are made on a case-by-case basis (a perfectly valid approach in areas of rapid development), there is the potential to drift away from what was intended by the

---

[49] Additional precautions included the following: (1) no one employed by or otherwise connected with the research could donate eggs; (2) potential donors were to receive full information about the scope and probable results of the research, including advice that the research would be unlikely to lead to clinical applications in the near future); and (3) potential donors were to receive information on potential risks of donation.

[50] RCL Minutes, 11 July 2006.

[51] For an example of the HFEA asserting a robust and purposive interpretation of its authority, see *Quintavalle v. HFEA*, [2005] UKHL 28. For a comment on this case, see S. Sheldon, "Saviour Siblings and the Discretionary Power of the HFEA" (2005) 13 Med Law Rev 403-411.

policy framework developed by the richer Parliamentary debates, particularly where the logic of interests is primarily relied on as opposed to the fuller range of typologies.

Second, and linked to this, the HFEA also serves as an advisory body, a function for which one might expect it to consider the broadest possible range of issues (and therefore call upon the full range of typologies). Of the (many) criticisms directed at the HFEA, those which seem particularly justified challenge its tendency to make policy on a case-by-case basis. Such an approach, demonstrated above, permits it to: (1) avoid broader debates reliant on a wider range of argument typologies; and (2) narrow the evidence on which it relies. For example, contrast the RLC's assessment of egg sharing to that undertaken elsewhere,[52] where, on the issue of remuneration (or reduced treatment costs), broader and better evidence has been brought to bear which suggests that couples seeking fertility treatment are often under immense stress, and can easily perceive coercion (even when no such intention exists), an issue barely noticed in the application.[53]

(3) Stem Cell Administration: Enforcing Boundaries in the Commercial Setting (Boundaries Re-Visited / Re-Hashed)

The last site we consider is that of administration in commercialisation, notionally a key intermediate step in the pipeline from initial idea to socially useful and publicly available ESC-based product/process (although products intended for human consumption/application must also navigate the safety standards regime which can take another 10 or more years). This site is occupied by a large number of actors, one of the most important of which is the EPO, which derives its authority from the European Patent Convention (1973)[54] (EPC), and has the multiple functions of supporting innovation, competitiveness and economic growth, strengthening European cooperation, and creating standard rules of treatment and procedure for the protection and commercialisation of inventions.[55] Under the EPC, patents can be challenged or "opposed" by any interested natural or legal person within nine months of the issuance of a patent.[56] The Opposition Division (OD) of the EPO reviews the patentability of opposed inventions on grounds specified in Article 102 EPC, and determines whether the patent can be maintained given the opponent's submissions.[57] Although they can be document-based reviews, oral hearings before the OD are not uncommon,[58] and it must render a decision which affirms, amends or revokes the

---

[52] See C. Roberts & K. Throsby, "Paid to Share: IVF Patients, Eggs and Stem Cell Research" (2008) 66 Social Science & Medicine 159-169, and S. Parry, "(Re)constructing Embryos in Stem Cell Research: Exploring the Meaning of Embryos for People Involved in Fertility Treatments" (2006) 62 Social Science & Medicine 2349-2359.

[53] Following this RLC decision, the HFEA undertook a public consultation on donating eggs for research, ultimately reporting that the majority of respondents were in favour of altruistic egg donations, but that this majority reduces when considering egg sharing (largely due to concerns around coercion): see HFEA, *Donating Eggs for Research: Safeguarding Donors* (2007), available at http://www.hfea.gov.uk/docs/donating_eggs_for_research_safeguarding_donors_consultation_FINAL.pdf.

[54] Available at http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/ma1.html.

[55] For more on the EPO and its purposes, see www.european-patent-office.org/epo/pubs/brochure/general/e/epo_general.htm.

[56] See Articles 58, 99(1) and 115 EPC, and Clause D-I-4, EPO *Guidelines for Examination*.

[57] See Note on Opposition Procedure in the EPO, [1989] OJ EPO 417.

[58] For more on the OD panel and opposition procedures, see EPC Articles 19, 99-104 and 113-126, Rules 55-63, *Implementing Regulations of the EPC*, and Parts D and E, EPO *Guidelines for*

patent based on the grounds of the opposition and the evidence tendered.[59]

Again, we might note that the EPO is not purely administrative. Rather it, and its OD, can be characterised as performing the functions of a "boundary organisation".[60] It sits between different social worlds; that of science and science regulation, on the one hand, and of commerce and intellectual property, on the other. The OD in particular is a site where scientists and entrepreneurs who wish to transition from the research setting to the commercial setting by patenting ESCR outputs might (and do) clash with both competitors and interested bodies who oppose, on a variety of grounds, their attempt to monopolise an invention. As such, the OD attempts to perform a role that is useful to a variety of stakeholders (antagonists), involving people from a variety of communities, including the legal profession in a mediating role, and it fulfils a function that would be difficult or impossible for either community to fulfil on its own.

Of course, within this role, the EPO can only consider actions and arguments within standardised formats. For example, patents can only be opposed on certain grounds, namely that the criteria for patentability have not been met, the disclosure is insufficient, or the claims are over-inclusive.[61] With respect to patentability, inventions must be novel, contain an inventive step and be amenable to industrial application, and it must not otherwise be unpatentable as, for example, contrary to morality or *ordre public*.[62] Though originally viewed as an infrequently used but necessary safeguard at the margins of the system, the morality provision has become an increasingly-utilised tool for managing/influencing innovation.[63] Similarly, opposition proceedings have also evolved; in 1985, the EPO stated that it would be wrong to regard oppositions as contentious proceedings between warring parties where the deciding body takes a neutral position;[64] by 1993, it described oppositions as "contentious proceedings between parties normally representing opposite interests, who should be given equally fair treatment".[65]

In this article, we examine the OD's Minutes of the Oral Proceedings dated 22 July 2002 (Minutes), and Written Decision dated 21 July 2003 (Decision) in *EDINBURGH / Animal Transgenic Stem Cells*,[66] a patent filed on 21 April 1994 and held by the University of Edinburgh. This claimed protection for a process for

---

Examination. See also G. Paterson, *The European Patent System: The Law and Practice of the European Patent Convention* (London: Sweet & Maxwell, 1997), Ch. 4.B.

59 See Article 113 EPC. For more on admissibility and taking of evidence, see Article 117 EPC, Rules 71-76, *Implementing Regulations of the EPC*, Clause E-IV-1, EPO *Guidelines for Examination*.

60 See for example D. Guston, "Boundary Organisations in Environmental Policy and Science: An Introduction" (2001) 26 Science, Technology & Human Values 399-408, contained in a special issue of that journal which focuses on boundary organisations.

61 See EPC Articles 52-57 (patentability), 83 (clarity of disclosure), and 61 and 123 (over-inclusiveness) and Clauses D-III-5 and D-V, EPO *Guidelines for Examination*.

62 Article 53 EPC.

63 For more on its origins and evolution, see O. Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Aldershot: Ashgate, 2005), at 23, 29-34 and 53, R. Witek, "Ethics and Patentability in Biotechnology" (2005) 11 Sci. Eng. Ethics 105-111, and E. Armitage & I. Davies, *Patents and Morality in Perspective* (London: IPI, 1994). According to Witek, the morality provision was included in the EPC without much debate because such provisions had been around domestically for some time. In the UK, it dated back to the *Statute of Monopolies 1624*, but was interpreted primarily in relation to sexual morality (ie: it was considered that the government should not have to publish obscene documents or instructions on how to perform acts which would constitute breaches of the peace).

64 *MOBIL OIL / Opposition by Proprietor*, [1985] OJ EPO 299 (Enlarged App Div).

65 *ROHM & HAAS / Power to Examine*, [1993] OJ EPO 408 (Enlarged App Div).

66 European Patent Application No. 94913174.2.

genetically modifying animal stem cells which offered a survival advantage over differentiated cells. Opposition proceedings were initiated by Germany, Italy, the Netherlands, and eleven other parties,[67] who opposed the patent on grounds that the patent (1) was over-broad, (2) lacked novelty and an inventive step, (3) contained insufficient disclosure, and (4) was contrary to morality and ordre public insofar as the term "animal stem cells" could include human ESCs.

With respect to arguments under the first three grounds, the proprietor was required to meet technical tests to demonstrate that it had fulfilled the conditions for patentability. As such, the claim that the patent was over-broad was addressed at the oral proceedings by correcting cited publications in the application. The claim that the patent lacked novelty and inventive step was addressed by examining the pre-existing published work and determining that the selectable marker system used by the proprietor demonstrated an advantage over the methods disclosed in the prior art. The claim that the patent contained insufficient disclosure was addressed through the scientific reproducibility of the patent claims advanced. In short, these issues were addressed using the special criteria and language of the patent regime and did not implicate the argument typologies outlined above. Rather, using terminology specially relevant to it as a boundary organisation, the EPO applied a series of boundary objects (legal tests which necessitate certain legal evidence) to establish whether the conditions for patentability had been met, thereby creating scientific and social order, and producing stability.

However, consideration of the morality provision gives rise to a realm capable of a completely different type of exchange; one where such order has yet to be produced and where stability has not yet been achieved. The morality provision states that (1) patents shall not be granted for inventions the exploitation of which would be contrary to morality or *ordre public*, and (2) inventions which concern the use of human embryos for industrial or commercial purposes are so contrary.[68] The OD defined morality as relating to the belief, founded on the deeply held and conventionally accepted norms of a particular society, that some behaviour is right/acceptable and some is wrong/unacceptable. With respect to identifying conventionally accepted norms, however, it stated:

> Neither the evaluation of the national legislation nor the assessment of the conventionally accepted standards of conduct of European culture has revealed a uniform approach with regard to human ESC, and … even a uniform estimation of the situation for all contracting states … would not automatically [suffice] under Article 53(a) EPC [to render an invention unpatentable]. …[69]

Given this, it noted that (1) patent law must be applied so as to respect the fundamental principles of dignity and integrity, (2) the illustrative list of unpatentable

---

[67] The Opponents were: (1) Greenpeace Deutschland e.V; (2) PDS-Bundestagfraktion; (3) Ökumenischer rat der Kirchen in Österreich; (4) Bundesrepublik Deutschland; (5) Alliance Pour les Droits de la Vie; (6) Aktion Leben Österreich; (7) Greenpeace e.V. Sammeleinspruch; (8) Bündnis 90 die Grünen – Bundestagfraktion; (9) Dr. Ruth Tippe; (10) Het Koninkrijk der Nederlanden; (11) Deutsche Forschungsgemeinschaft; (12) Regierung der Republik Italien; (13) Dr. Jürgen Kaiser; (14) Bündnis 90 die Grünen.

[68] See Article 53(a) EPC, and Rule 23d(c), which states: "Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern uses of human embryos for industrial or commercial purposes."

[69] OD Decision, Para. 2.5.3.

inventions (in the EU Directive 98/44/EC) is not exhaustive and can be expanded, and (3) although inventions using human embryos for industrial/commercial purposes are unpatentable, inventions for diagnostic or therapeutic purposes which are applied and are useful to the embryo are excepted.

Against this background, the Opponents deployed a variety of arguments. Some very few deployed a Core Values typology insofar as they challenged the desirability of research on embryos. For example, one Opponent argued that "embryo research should be allowed for medical reasons only, and this patent would provide a commercial incentive for research into and experiments using human embryos".[70] Similarly, one Opponent argued from an Evidence-to-Consequences perspective, introducing herself as a children's author, owner of a small publishing firm for children's books, children's advocate, and grandmother, emphasising that she was worried about the future, the environment and nature, which would become more and more artificial, and then pleading against the grant of life patents.[71] More often, Opponents argued from a Competing Interests typology. For example:

- The protection of humans has to be given priority over the patenting of biotechnological inventions and scientific interests.[72]

- The proprietor provided no evidence indicating prior informed consent on the part of those from whom this biological material was taken, nor did it indicate whether there was any profit motive involved in giving consent, and thus it cannot be said to have complied with *ordre public*.[73]

- Germany, Italy and the Netherlands comprise some 200 million EU citizens who are opposed to this patent, thereby outnumbering supporters.[74]

The proprietor responded that the research was conducted in the UK under licence and that it had complied with statutory requirements re: consent procedures, and it was not the role of the EPO to act as a moral censor or to refuse a patent on legal research. Moreover, it argued that the subject patent did not require human embryos, and while UK legislation prohibited the commercialisation of embryos, it did not prohibit this invention.[75] In short, core values had been considered elsewhere and patentability was supported by the EGE and other authorities, and competing interests had been arbitrated by national legislation, and had been protected.

Although the expectation might be that the OD would need to engage with core values re: the morality of commercialising inventions derived from ESC research, its approach suggests that it considered the core values engagement to have taken place elsewhere (eg: the debates around the adoption of the EPC, Directive 98/44/EC, and national legislation). Despite an underlying concern for core values such as human dignity, core values were actually relegated to vague background ideas against which the real debate was the interpretation of the intention behind the various

---

70 OD Minutes of Oral Proceedings, p. 17, section 15.1.

71 *Ibid*, p. 22, section 15.6.

72 *Ibid*, p. 20, section 15.3.

73 *Ibid*, p. 21, section 15.4.

74 *Ibid*, p. 18, section 15.1. Although the OD is to have recourse to conventionally accepted standards of conduct in the EU, it rejected this argument outright on the basis that the EPC and the Implementing Regulations made measurements irrelevant: see *ibid*, p. 26, section. 22.

75 *Ibid*, p. 23-24, section 17.

EPC provisions ie: it was not prepared to engage with substantive ethical issues. As such, it gave little weight to the few arguments from the Core Values typology, and scant more weight to the arguments from the Evidence-to-Consequences typology. As suggested above, the main assessment undertaken by the OD was an instrumental one concerned with the source(s) for boundary-setting and the interpretation of those sources.

In addition to the arguments of the parties, the OD made reference to Opinion 16 of the European Group on Ethics in Science and New Technologies (EGE),[76] a 15-member panel of EU-appointed advisors which undertook a round-table consultation, held four expert hearings, and commissioned two reports. With respect to the morality of ESCR itself, the EGE had previously stated that respect for different philosophical, moral, or legal approaches, and for diverse cultures, is a necessary ethical dimension of building a democratic European society and as such, although some countries forbid ESCR, where it is allowed for the purpose of developing new treatments to cure infertility, severe diseases or injuries, it is "hard to see any specific argument which would prohibit extending the scope of such research".[77] With respect to patenting such research, the EGE, deploying a Competing Interests type argument, claimed that the consequences of forbidding SC and SC-line patenting would be a major slowing of research contrary to public and patient interests.[78] The bulk of its argument, however, adopted the language of the boundary organisation rather than that of the ethical arena. For example, it opined that:[79]

- isolated SCs should not be patentable as this may be considered a form of commercialisation of the human body and would lead to over-broad patents as they have a number of different potential uses;

- SC lines which have been modified (genetically or otherwise) should be patentable; and

- processes involving human SC have no special ethical obstacles and should be patentable.

This Opinion was then evaluated by the OD on the basis of its compliance with concepts defined by the OD's boundary tools, and it was found wanting; the OD identified a number of discrepancies and problems in the arguments made, concluding rather dismissively that, "due to its many inconsistencies, logical flaws, and incompatibility with existing patent law and the EU Directive, the Opinion must be disregarded *in toto*."[80] In the end, it concluded that the exception to patenting, which

---

[76] EGE, *Opinion 16: Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (2002), at http://ec.europa.eu/european_group_ethics/docs/avis16_en.pdf.

[77] EGE, *Opinion 15: Ethical Aspects of Human Stem Cell Research and Use* (2000), at http://ec.europa.eu/european_group_ethics/docs/avis15_en.pdf, at 15-16.

[78] *Ibid*, at 14, para. 2.1.

[79] EGE, *supra*, note 74, at 15.

[80] OD Minutes of Oral Proceedings, p. 25, section 2.5.4. The tragedy of the EGE Opinion was that it was utterly dismissed. This may have been, in part, because of a mismatch in the discursive typologies used between the EGE and the OD (ie: the "language" of the EGE was not translatable into OD action and its use of patenting "language" was not deemed acceptable by the OD). All of this despite the fact that the EPO was apparently involved in the pre-Opinion round table. Note that the EGE has given notice of its desire to revisit the issue of patenting biological materials: see EGE,

had traditionally and fairly consistently been interpreted very narrowly, deserved a wider interpretation, thereby expanding its scope and potential impact.[81] In the result, the main request of the proprietor was not allowed in its original form (ie: it had to be amended and limited to mouse ESCs). The proprietor subsequently appealed,[82] but the appeal was eventually withdrawn at oral proceedings held on 20 November 2007.[83]

For present purposes, we can conclude that the EPO is clearly uncomfortable with the utilisation of the subject typologies, preferring a more instrumental assessment within the parameters of its boundary tools. This is amply demonstrated by its approach to the morality provision, which it appears unable or unwilling to apply robustly, even in cases concerning controversial biotech inventions over which societal views diverge. In this respect, the EPO exhibits what might be called "regulatory atrophy". Despite its attempt to incorporate Directive 98/44/EC into its processes, it continues to rely on an instrument and a decision-making framework from the past pre-biotech revolution, and has yet to (re)fashion its boundary tools (or more accurately its decision-making frameworks) to fit the modern context. A more relevant boundary tool, given the legal responsibilities of the EPO and the increasingly contested nature of the inventions over which it must adjudicate, might direct it to adopt a wider assessment, offer it the possibility of better evidence, and ensure that it considers both innovator and wider social aspirations.

(4) Summation

Our assessment of the governance of SCs at these three sites disclose rather large variations in the utilisation of arguments of different types. The first (and final) arbiter of whether ESCR should be permitted appears to be Parliament, and it is here that the greatest variety of arguments and values are brought to bear. Afterwards, the prevalence of the different typologies (and their effectiveness) is somewhat circumscribed. This is not altogether surprising (or troubling) when one considers the primary nature and purpose of these other sites, and the primary roles and functions of their institutions, which are smaller, appointed, and more circumscribed in jurisdiction. However, it is important to recall that even these more limited institutions (eg: the HFEA and EPO) are not purely instrumental or policy-implementing; they have broader functions in contested areas which arguably necessitate deeper and more detailed assessments, and therefore a broader range of legal evidence than they have been soliciting. Given the pace of technological change, the bodies applying a narrow range of typologies of argument could be in danger of regulatory drift (HFEA) or regulatory atrophy (EPO). In both cases, but particularly with respect to the HFEA, which has a foot in both policy-making and administrative arenas, there is room (and probably a need) to encourage and engage with a wider range of discursive styles (in challenging cases) while at the same time relying on defined and implementable values and tools.

Opinion 22: Recommendations on the Ethical Review of hESC FP7 Research Projects (2007), at http://ec.europa.eu/european_group_ethics/activities/docs/opinion_22_final_follow_up_en.pdf, at 46.

[81] For more on the previous narrow interpretation and the subsequent wider interpretation of the exception, see S. Harmon, "The Rules of Re-Engagement: The Use of Patent Proceedings To Influence the Regulation of Science ('What The Salmon Does When Comes Back Downstream')" (2006) 4 IPQ 378-403.

[82] See Statement of Grounds of Appeal dated 30 September 2003, and Appeal Submissions dated 31 March 2005.

[83] See EPO Letter Confirming Withdrawal of Appeal dated 26 November 2007.

CONCLUSION

We set out to examine the deployment of three different discursive typologies – Core Values, Evidence-to-Consequence and Competing Interests – in three different settings of ESC research – the political, the hybrid (policy-administrative) and the commercial. Our analysis demonstrates that, at least in the context of the examples studied, the way in which these typologies are deployed in the different sites varies greatly.

Perhaps not unexpectedly, indeed appropriately, the fullest range of typologies were evident in the political setting. We examined some of the Parliamentary debates on embryonic and ESCR, but of course the political setting includes a wider range of activities than simple debates so we might expect the range of arguments made to be even greater than considered herein. Insofar as biotechnologies (and ESCR-based technologies) are deemed to challenge core values and norms, Parliamentary debates should and apparently do provide a space for extensive deliberation and the bringing to bear of all manner of arguments. This is encouraging insofar as we can extrapolate from the presence of all typologies that a variety of values, interests, evidence and concerns were considered and played their part in the formation of the law. And this, of course, suggests that democracy in science, and indeed democracy more broadly, both as practices and as social values, is being realised on the ground.

Having considered and established the legal boundaries for research, Parliament has left it to the HFEA to enforce those boundaries in its licensing of proposed laboratory research. Given its dual role as policy advisor and administrator, one might have expected the HFEA to entertain a process which engages all typologies. However, with respect to its licensing process, and based on the limited evidence available, it seems unprepared to draw on wider sources and diverse typologies, preferring instead to rely almost exclusively on the Competing Interests typology.[84] Of course, we recognise that a licensing procedure must be reasonably quick, efficient, cost-effective and reproducible over time, and, as such, must be both focused and circumscribed in its scope (ie: the acceptance of every manner of argument would likely stretch the process beyond the statutory criteria). However, the arguments and evidence to which the HFEA becomes privy through its other role (policy-advisor) could be raised in the licensing setting to enrich that process and the basis upon which decisions are made therein.[85] Such was not found.

In the modern setting, the potential for commercialisation is seen as essential to the instigation of health innovation. An important element of that commercialisation is the patenting of inventions. As noted above, ESC research-based inventions are controversial and have prompted opposition proceedings within the EPO. However, based on the evidence reviewed, the OD appears to expect that arguments of all typologies have taken place elsewhere, permitting it to adopt a more limited and instrumental process, one which avoids engaging with the sort of debate

---

[84] This is perhaps not surprising given the long history in medical ethics of protecting research subjects in medical research by balancing their autonomy and safety interests against the researchers' and society's interests, from the Nuremburg Code, to the Helsinki Declaration, and so on.

[85] And we have already noted above the example of the diverse and insightful arguments around egg-sharing, arguments and evidence which the HFEA apparently ignored in its consideration of an egg-sharing request by a licensee. Having said that, it could be argued that the HFEA's policy advice role should not seep into its licensing functions, but rather should be realised by delivering opinions to government and/or indicating to government that a review of existing policy is timely.

that would support deployment of the subject typologies. Again, this might normally be acceptable in the traditional administrative setting, but the EPO has been assigned an adjudicative function over an issue which is clearly value-driven and amenable to a range of argument types (morality), making its failure to be more responsive a failure to robustly exercise its remit.

Given the above, although sites with different primary objectives might be expected to have different ways of arguing, we suggest that existing practices do not match existing remits (at least with respect to the EPO and, to a lesser extent, the HFEA), as defined by their empowering instruments.[86] The mismatch (between remit and conduct) of these latter two institutions suggests that the values of science democracy and justice are not being as well realised as they might be, or indeed should be, as suggested by their empowering instruments. Implementation of legislation in a fast-moving field such as biotechnologies like ESC research can be problematic. The HFEA's dual role offer one method of dealing with this reality, but there is a danger of regulatory drift (and, in any event, we would suggest based on the limited evidence considered that it isn't managing that fusion very well). The EPO, though sitting more squarely in the administrative setting, has also been empowered to engage with a variety of typologies, but is also failing to cope very well, with the result that it is experiencing regulatory atrophy. In some senses the HFEA and the EPO represent opposite sides of the spectrum in dealing with this situation.

Stakeholders and publics are likely to deploy more than one typology in any particular setting (so long as the setting permits it), but their world view naturally channels them to emphasise certain values (to the detriment of others) in whatever typology they employ. Stakeholders dissatisfied with existing practices or trajectories are likely to employ all of the channels and typologies available to them to secure change. This means that both the HFEA and the EPO are likely to continue to face cases and arguments with which they are uncomfortable, and to be challenged about their decisions in those cases. The fact is that, regardless of the site, biotechnological praxis raises contentious issues which need to be negotiated (and, because of their value-laden nature, re-negotiated). Although different regulatory instruments and organisational structures encourage different values and interests, those operating in the biotechnology environment need to be prepared to engage with different norms.

---

[86] This can be contrasted with their fulfilment of their roles as defined by stakeholder expectation, which may well be largely satisfied. Here one should recognise that stakeholders views are often very much situated in their particular context, and so may well share the same blinders that naturally limit the administrative agencies with which they interact.